IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO. 5:17-CV-616-FL

UNITED STATES OF AMERICA and THE STATE OF NORTH CAROLINA, ex rel. SANTHOSH REDDY DEVARAPALLY, M.D., Plaintiffs, v. FERNCREEK CARDIOLOGY, P.A.; MATTHEW A. DAKA, M.D.; SELVARATNAM SINNA, M.D.; SURIYA BANDARA JAYAWARDENA, M.D.; and MANESH THOMAS, M.D., Defendants.	)	ORDER

This matter is before the court on defendants' motions for summary judgment (DE 114, 117, 125, 127, 129). Also before the court are plaintiffs' motion to strike opinions of defendants' experts (DE 112) and defendants' motion to strike opinions of plaintiffs' experts (DE 131). The motions have been briefed fully, and in this posture, the issues raised are ripe for ruling. For the following reasons, all of the motions before the court are denied.

STATEMENT OF THE CASE

Relator Santhosh Reddy Devarapally, M.D. ("relator"), who is a cardiologist formerly employed by defendant Ferncreek Cardiology, P.A. ("Ferncreek"), commenced this False Claims Act case with sealed complaint filed December 13, 2017.[1] Relator asserted initially claims on

[1] The False Claims Act allows a person to bring a civil action "for the person and for the United States Government," wherein, as here, "[t]he action shall be brought in the name of the Government." 31 U.S.C. §

behalf of the State of North Carolina and the United States (collectively, the "governments") and himself, under the False Claims Act and the North Carolina False Claims Act ("NCFCA"), N.C. Gen. Stat. § 1-605, et seq., claiming defendants submitted false claims and made false statements in connection with medically unnecessary services over a period of about three years.

Upon motions by relator and the governments, the court extended the time to intervene eight times, until October 18, 2021. On that date, the court unsealed the case and allowed the governments to intervene in part and to decline to intervene in part.[2] Thereafter, the court denied a motion to dismiss by defendants,[3] and a period of discovery followed. With leave to amend, plaintiffs filed the operative amended complaint February 28, 2024,[4] asserting the following causes of action under the False Claims Act and the NCFCA: 1) submission of false claims, 2) false statements material to a false claim, and 3) conspiracy; and additional claims under North Carolina law, as follows: 4) common law fraud, 5) unjust enrichment, and 6) payment by mistake.[5] Plaintiffs seek treble damages, civil penalties, costs, and interest.

3730(b)(1). The government thereafter may elect to "proceed with the action, in which case the action shall be conducted by the Government; or . . . notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action." Id. § 3730(b)(4). Although the terms "relator" and "ex rel." are not defined in the statute, they are the names commonly used to denote a private individual suing on behalf of the government under the False Claims Act. See, e.g., United States ex rel. Doe v. Credit Suisse AG, 117 F.4th 155, 158 & n.1 (4th Cir. 2024) ("The FCA contains the 'unusual' feature of allowing private parties, known as 'relators,' to sue on the government's behalf by bringing qui tam actions.").

2 The governments submitted a sealed motion and supporting memorandum for each extension of time to intervene. On June 13, 2024, the court denied defendants' motion to unseal and granted plaintiffs' motion to maintain those memoranda under seal. (DE 107).

3 See United States ex rel. Devarapally v. Ferncreek Cardiology, P.A., No. 5:17-CV-616-FL, 2023 WL 2333872, at *1 (E.D.N.C. Mar. 2, 2023). This matter was initially assigned to the Honorable W. Earl Britt, Senior United States District Judge. The matter was reassigned to the undersigned June 2, 2022.

4 All references to the complaint or "compl." in citations herein are to the operative amended complaint in intervention (DE 89).

5 Plaintiffs state in opposition to the instant motions for summary judgment, that they withdraw their state law claims of common law fraud, unjust enrichment, and payment by mistake, and certain portions of their claims for damages under the False Claims Act and the NCFCA. The court addresses the claims remaining in the analysis herein.

Plaintiffs filed the instant motions to strike opinions of defendants' experts Cam Patterson, M.D. ("Patterson"), Matthew Holland, M.D. ("Holland"), and Bryan Callahan, ("Callahan"), September 10, 2024, relying upon expert reports of Ian Gilchrist, M.D. ("Gilchrist"), Michael J. Petron ("Petron"), Patterson, Holland, and Callahan; and deposition excerpts of Patterson, Holland, and Callahan. Defendants responded in opposition, and plaintiffs replied.

Defendants filed the instant motions to strike opinions of plaintiffs' experts Gilchrist and Petron September 10, 2024. Plaintiffs responded October 1, 2024, relying upon expert reports of Gilchrist and Petron; excerpts of depositions of Gilchrist, Holland, defendant Manesh Thomas M.D. ("Thomas"), and Robert D'Zio ("D'Zio"); affidavit of Petron; correspondence from KEPRO;[6] and a coronary artery disease study. Defendants replied.

Defendants filed the instant motions for summary judgment, also on September 10, 2024, relying upon individual statements of material facts and collective appendix including the following exhibits and categories of exhibits: 1) depositions of defendants Defendant Suriya Bandara Jayawardena, M.D. ("Jayawardena"), Matthew A. Daka, M.D. ("Daka"), Selvaratnam Sinna, M.D. ("Sinna"), and Thomas (collectively, the "individual defendants"); relator, D'Zio, Petron, Gilchrist, Craig Schiffbauer ("Schiffbauer"), Jennifer Romano ("Romano"), Patterson, Holland, and Callahan; 2) documents and correspondence, including letters and faxes to and from KEPRO, emails from Romano and defendant Thomas, relator's termination notice, provider enrollment applications, and subpoena and request for information from the United States

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[6] "KEPRO" is shorthand for "Keystone Peer Review Organization, Inc.," which serves as North Carolina "Medicaid's Comprehensive Independent Assessment Entity." See Transition Dates Announced for NC Medicaid's Comprehensive Independent Assessment Entity, NC Medicaid Division of Health Benefits (Sept. 18, 2023), https://medicaid.ncdhhs.gov/blog/2023/09/18/transition-dates-announced-nc-medicaids-comprehensive-independent-assessment-entity [https://perma.cc/53JV-NGEF]. KEPRO is categorized by the United States Centers for Medicare & Medicaid Services as a "beneficiary and family centered care quality improvement organization." Contacts Database, Centers for Medicare & Medicaid Services, https://www.cms.gov/contacts/kepro/general-beneficiary-contact/1550896 [https://perma.cc/UQ9Q-XD67].

Department of Health and Human Services Office of Inspector General; 3) expert reports of Gilchrist, Petron, Holland, and Patterson; 4) plaintiffs' privilege log; 5) American Medical Association Current Procedural Terminology ("CPT") codes for years 2014 through 2019; 6) patient transaction reports for patients JA, HD, RM, ET, RB, JB, JH, JS, JH, and AH; 7) affidavit of Callahan; and 8) three unredacted spreadsheets filed manually under seal.

Plaintiffs responded in opposition October 1, 2024, relying on statements of material facts and appendix including the following exhibits or categories of exhibits: 1) excerpts of depositions of individual defendants, relator, D'Zio, Gilchrist, Holland, and Romano; 2) affidavits of Muhammad Marwali, M.D. ("Marwali") and Petron; 3) expert reports of Gilchrist and Petron; 4) documents and correspondence, including a report titled "Expert Consensus Statement on the Use of Fractional Flow Reserve, Intravascular Ultrasound, and Optical Coherence Tomography," letters from KEPRO and Humana, and emails between Romano and Stephen C. Rose; 5) defendants Ferncreek, Daka, Sinna, and Thomas's responses to plaintiffs' first request for admissions; and 6) a slideshow titled "Ferncreek Cardiology Providers Performance." Defendants replied October 15, 2024.

STATEMENT OF UNDISPUTED FACTS

The undisputed facts as pertinent to the analysis herein may be summarized as follows.

A. Allegedly False Claims

Defendant Ferncreek is a Professional Association that provides cardiology services to patients in Fayetteville, North Carolina. (Pls' Stmt. (DE 137) ¶ 1).[7] The individual defendants are board-certified cardiologists who owned Ferncreek from 2014 to 2018. (Id. ¶¶ 2-5, 8). Relator

[7] Where a fact asserted in the movants' statement of material fact is undisputed, the court cites to the opposing parties' responsive statement of facts, where it indicates the fact is admitted, undisputed, or without opposing fact.

worked for Ferncreek as a cardiologist during 2014 and 2015. (Id. ¶¶ 9-11). Romano is Ferncreek's office manager. (Id. ¶ 6).

During the years in question, between 2014 and 2017, defendants provided cardiology services to a population of patients with "a high prevalence of cardiovascular risk factors." (Pls' Stmt. (DE 137) ¶ 18). Coronary artery disease ("CAD") is a common type of heart disease, and it can be diagnosed via coronary catheterizations, which are performed in a hospital setting. (Id. ¶ 19). Defendants performed heart catheterizations at Cape Fear Valley Medical Center ("Cape Fear"). (Id. ¶ 27). Peripheral artery disease ("PAD") is a separate condition, affecting blood flow to a person's extremities. (Id. ¶ 20). PAD can be diagnosed via peripheral angiogram or leg catheterization, which are performed in hospital or office settings. (Id.). A doctor's decision to perform a leg catheterization or PAD procedure depends on the patient's symptoms and prior test results. (Id. ¶ 80). Similarly, decisions regarding cardiac catheterization and stents are multi-factorial and patient dependent. (Id. ¶ 78).

Healthcare professionals use CPT codes to report medical, surgical, and other services to public and private health insurers. (Id. ¶ 21). The CPT codes for the procedures at issue here are as follows:

36247	"initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within vascular family"
93454	"catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation"
93458	"with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed"
93459	"with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography"

92928	"percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch"

(Id. ¶¶ 22-26).

Defendants Daka, Thomas, and Jayawardena performed invasive and interventional procedures, while defendant Sinna and relator performed invasive diagnostic procedures only. (Id. ¶ 15).

On May 18, 2017, KEPRO sent defendant Ferncreek a letter regarding "Initial Sanction Notice of Substantial Violation in a Substantial Number of Cases." (Id. ¶ 86; DE 121-14). The letter included a list of patients, four of whom had been treated by defendant Thomas, for which "KEPRO peer reviewers questioned if there was appropriate documentation." (Pls' Stmt. (DE 137) ¶¶ 87-88; DE 121-14 at 4-7).[8] Following a meeting with KEPRO, defendant Thomas agreed to participate in a corrective action plan, wherein he would submit ten random cases per month with a review by a peer of his choice. (Pls' Stmt. (DE 137) ¶ 91). KEPRO sent defendant Ferncreek a letter January 10, 2019, stating that the corrective action plan had been successfully completed. (Id. ¶ 93; DE 121-23).

According to plaintiffs, defendant Ferncreek also entered a coding improvement plan with Humana on May 3, 2017. (Pls' Stmt. (DE 137) ¶ 140; DE 139-16).

B. Governments' Investigation

When relator initiated this action, he identified patients of defendants upon whom he alleged medically unnecessary procedures were performed. (Id. ¶¶ 28-29). Special Agent Madeline Fillman, who is now retired, initiated the governments' investigation of relator's

[8] Unless otherwise specified, page numbers in citations to the record in this order refer to the page number of the document designated in the court's case management / electronic case filing (CM/ECF) system, and not to page numbering, if any, specified on the face of the underlying document.

complaint in 2017. (Pls' Stmt. (DE 137) ¶¶ 32-33). Special Agent Schiffbauer joined the investigation in 2018. (Id. ¶ 34).

As part of the investigation, Schiffbauer requested Safeguard Services LLC ("Safeguard") to prepare a statistical sample of defendant Ferncreek's patients. (Id. ¶ 36). Alina Moya ("Moya") was the statistician at Safeguard who prepared the requested sample. (Id. ¶ 37). Although Moya is now retired and unavailable for deposition, plaintiffs assert the Safeguard files produced in discovery "provided information setting out how [Moya] created the samples at issue." (Id.). Safeguard statistician D'Zio performed quality control of the samples prepared by Moya. (Id. ¶ 38).

Safeguard prepared two samples in February 2019. (Id. ¶ 43). The first sample included 84 coronary catheterization claims under CPT codes 92928, 93458, 93459, and 93454 (the "CAD sample").[9] (Id. ¶¶ 44, 49). The second sample included 42 catheterizations into abdominal pelvic or leg artery claims under CPT code 36247 for which "there were no noninvasive extremity arterial studies billed within 30 days prior" (the "PAD sample").[10] (Id. ¶¶ 45, 52). Both samples cover the date range January 2014 to December 2017. (Id. ¶¶46-47). Plaintiffs assert these are "statistically valid random sample[s]." (Id. ¶ 105).

The methodology Moya used to prepare the CAD and PAD samples stated 90% confidence level and 10% expected precision. (Id. ¶ 48). The parties dispute whether the respective sample sizes of 84 and 42 achieve 90% confidence. (Id. ¶¶ 49, 53). According to defendants, the samples achieve "slightly more than 80% confidence." (Defs' Stmt. (DE 116) ¶¶ 49, 53). Plaintiffs assert

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9 The procedures in this sample are used to diagnose or treat coronary artery disease ("CAD").

10 The procedures in this sample are used to diagnose or treat peripheral artery disease ("PAD").

the sample sizes are sufficient for a one-sided 90% confidence level, and "a one-sided 90% is equivalent to a two-sided 80%." (Pls' Stmt. (DE 137) ¶¶ 49, 53). According to D'Zio, the "methodology and sample size were adequate to achieve the 90 percent confidence based upon the software program simulation that [Moya] ran." (Id. ¶ 61).

Plaintiffs requested from defendant Ferncreek patient records for the patients included in the CAD and PAD samples. (Id. ¶¶ 63, 64). Schiffbauer also requested information from Cape Fear. (Id. ¶ 69).

Plaintiffs retained Gilchrist, a cardiologist, to review the procedures in the CAD and PAD samples. (Id. ¶ 94). Gilchrist identified 23 CAD procedures and 7 PAD procedures within the samples that he determined were not reasonable and necessary. (Id. ¶ 96). The identified CAD procedures were performed by defendants Daka, Thomas, Jayawardena, and Sinna, and the identified PAD procedures were performed by defendants Daka, Thomas, and Jayawardena. (Id. ¶ 97). According to plaintiffs, the total amount of Medicare[11] and Medicaid[12] claims paid for the identified CAD and PAD procedures was $18,506. (Id. ¶ 187).

According to plaintiffs, the individual defendants "admitted that their claim forms certified that 'the services on this form were medically necessary' and understood there were consequences to false certifications." (Id. ¶ 98). Also according to plaintiffs, the individual defendants "admitted that they knew they were required to maintain adequate medical records to justify the claims submitted to Medicare and Medicaid." (Id. ¶ 100).

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11 The Health Insurance for Aged and Disabled Program, commonly known as "Medicare," was established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395, et seq.

12 The Medicaid Program ("Medicaid") was established by Title XIX of the Social Security Act, 42 U.S.C. § 1396, et seq. Each state must have a single state agency to administer Medicaid within the state. Id. § 1396a(a)(5). The North Carolina Department of Health and Human Services, Division of Health Benefits administers Medicaid in North Carolina. See N.C. Gen. Stat. § 143B-216.80.

C. Expert Opinions

1. Gilchrist

Gilchrist is an interventional cardiologist and professor of medicine at Penn State University's College of Medicine. (Gilchrist Rep. (DE 122-1) at 7-8). He prepared a report in which he opines 23 CAD procedures performed by the individual defendants "appeared to be not reasonable or necessary," and that this total "appears far more than what would be expected in a random retrospective chart review." (Id. at 3). Gilchrist also opined that seven PAD procedures performed by defendants Daka, Jayawardena, and Thomas "appeared not reasonable," and that the large number of peripheral angiograms which did not result in further intervention "appear[ed] excessive and suggestive of over testing that is not reasonable or necessary." (Id.)

2. Petron

Petron is a certified public accountant and a certified fraud examiner. (Petron Rep. (DE 122-2) ¶ 1). He prepared a report in which he opined that Safeguard "created valid statistical samples that follow generally accepted statistical guidelines." (Id. ¶ 21). Relying upon Gilchrist's opinion of procedures that were not reasonable or necessary, Petron extrapolated both samples to estimate total overpayments of $313,512 for CAD procedures and $28,215 for PAD procedures. (Id. ¶¶ 22-26).

3. Patterson

Patterson is a board-certified cardiologist and professor of cardiovascular medicine at UAMS Health. (Patterson Rep. (DE 124-4) ¶ 2). He prepared a report in which he opines that "the general practice of Ferncreek Cardiology in selection of patients for cardiac catheterization [and peripheral arterial procedures] was similar to other practices in the area and generally not outside the standard of care." (Id. ¶ 1).

4. Holland

Holland is a clinical cardiologist and associated professor at the University of Colorado School of Medicine. (Holland Rep. (DE 124-3) at 2). He prepared a report in which he opines that "the decisions made by the physicians of Ferncreek Cardiology were appropriate," and "the care provided to [their] patients was both thoughtful and excellent." (Id. at 5).

5. Callahan

Callahan is a certified public accountant and certified fraud examiner, certified in financial forensics. (Callahan Rep. (DE 113-6) ¶ 14). He prepared a report for defendants in which he opines that "the conclusions reached by Mr. Petron rely upon flawed and incomplete assumptions." (Id. ¶ 19).

DISCUSSION

A. Motions to Exclude Expert Testimony

Because testimony from the parties' expert witnesses is pertinent to the resolution of the motion for summary judgment, the court first discusses the motions to exclude before engaging in summary judgment analysis.

1. Standard of Review

Under Federal Rule of Evidence 702, expert testimony is appropriate when "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. A witness qualified as an expert may be permitted to testify where "(b) the testimony is based upon sufficient facts or data, (c) the testimony is the product of reliable principles and methods, and (d) the expert has reliably applied the principles and methods to the facts of the case." Id. Rule 702 imposes a "basic gatekeeping obligation" upon a trial judge to "ensure that any and all scientific testimony is not only relevant,

but reliable." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147 (1999); Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 592-93 (1993).[13]

"A witness's qualifications are liberally judged by Rule 702, and a person may qualify to render expert testimony in any one of the five ways listed by the rule." Kadel v. Folwell, 100 F.4th 122, 158 (4th Cir. 2024). Those ways are "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an opinion." Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 799 (4th Cir. 1989).

"[R]elevance – or what has been called 'fit' – is a precondition for the admissibility of expert testimony, in that the rules of evidence require expert opinions to assist the 'the trier of fact to understand the evidence or to determine a fact in issue.'" United States v. Ancient Coin Collectors Guild, 899 F.3d 295, 318 (4th Cir. 2018) (quoting Daubert, 509 U.S. at 597). A key "aspect of relevancy ... is whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Daubert, 509 U.S. at 591.

The reliability inquiry is a "flexible one focusing on the principles and methodology employed by the expert, not on the conclusions reached." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999). In assessing whether expert testimony is "reliable," the court may consider:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the techniques' operation; and (5) whether the technique has received general acceptance within the relevant scientific or expert community.

[13] Throughout this order, internal citations and quotation marks are omitted from citations unless otherwise specified.

United State v. Crisp, 324 F.3d 261, 266 (4th Cir. 2003). These factors are "neither definitive, nor exhaustive," and "particular factors may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199–200 (4th Cir. 2001). "[T]he court has broad latitude to consider whatever factors bearing on validity that the court finds to be useful[,] ... depend[ing] upon the unique circumstances of the expert testimony involved." Westberry, 178 F.3d at 261. To be reliable, an expert opinion must be "based on scientific, technical, or other specialized knowledge and not on belief or speculation." Oglesby v. Gen. Motors Corp., 190 F.3d 244, 250 (4th Cir. 1999). "An expert's opinion should be excluded when it is based on assumptions which are speculative and are not supported by the record." Tyger Constr. Co. Inc. v. Pensacola Constr. Co., 29 F.3d 137, 142 (4th Cir. 1994).

"The proponent of the testimony must establish its admissibility by a preponderance of proof." Cooper, 259 F.3d at 199. Review by the advisory committee indicates that rejection of expert testimony is the exception rather than the rule. Fed. R. Evid. 702 advisory committee's note to 2000 amendment. "[Q]uestions regarding the factual underpinnings of the expert witness' opinion affect the weight and credibility of the witness' assessment, not its admissibility." Bresler v. Wilmington Trust Co., 855 F.3d 178, 195 (4th Cir. 2017).

Additionally, every retained expert witness must provide a report containing "a complete statement of all opinions the witness will express and the basis and reasons for them," as well as "the facts or data considered by the witness in forming" those opinions. Fed. R. Civ. P. 26(a)(2)(B)(i-ii). "The purpose of Rule 26(a) is to allow litigants to adequately prepare their cases for trial and to avoid unfair surprise." Bresler, 855 F.3d at 190.

2. Analysis

a. Gilchrist

Gilchrist is a board-certified interventional cardiologist, and defendants do not challenge his qualifications or the relevance of his testimony. Gilchrist has sufficient specialized knowledge to qualify as an expert, and his opinions are relevant to the factual question whether defendants submitted claims for procedures that were not reasonable and necessary. Therefore, Gilchrist's testimony is admissible if the principles and methodologies he employed are reliable. See Westberry, 178 F.3d at 261. The court concludes that they are.

Gilchrist's report sets out his opinion on the medical necessity of the 126 procedures included in the CAD and PAD samples. After carefully reviewing the medical records of patients in the care of defendants, Gilchrist determined that four CAD stent procedures were performed based on gross over-estimation of the stenosis/blockage percentage, five CAD stents were improperly justified by intravascular ultrasound rather than angiographic images, nine CAD stents were not necessary based upon other clinical grounds, five CAD catheterizations were not medically necessary based upon the medical records, and seven PAD catheterizations were medically unnecessary based upon normal tests and medical records. (Gilchrist Rep. (DE 140-2) at 2).

Defendants argue that Gilchrist's testimony regarding the stents justified by intravascular ultrasound is unreliable because it is in part based on a false assumption that alternative diagnostic tools were available to defendants at the time these procedures were performed. (See Defs.' Mem. Supp. Mot. Strike (DE 132) at 16-17). This argument fails. Gilchrist opines that defendants improperly relied upon intravascular ultrasound to justify placement of five CAD stents. (See, e.g., Gilchrist Rep. (DE 122-1) at 11). According to Gilchrist, "[g]uidelines do not support the use

of [intravascular ultrasound] in this fashion," and the "[s]tandard approach is to" rely upon "stress test or iFR/FFR[14] evaluation." (Id.). This is an application of the relevant guidelines to the facts presented to Gilchrist in the patient records, and, contrary to defendants' assertion, this opinion is not based on the availability of iFR or FFR to defendants. Gilchrist's testimony regarding the five stents justified by intravascular ultrasound is reliable.

Defendants' argument that Gilchrist failed to conduct a thorough review is unpersuasive, as he reviewed the records that were made available to him by defendants and formed an opinion based on his medical expertise:

> Each of the procedural episodes was reviewed. Indications were derived from review of office and hospital encounters prior to the procedure and notes from the time of the procedure. The actual procedures were reviewed by reading the transcript accounts both from the physicians and technically staff. The images from the procedures were then correlated to the activities documented in the notes to understand the indication for interventional procedures that may have been dependent on the diagnostic imaging obtained during the initial part of the procedure.

(Gilchrist Rep. (DE 122-1) at 3). Based on Gilchrist's "specialized knowledge" in cardiology, this methodology is reliable. See Oglesby, 190 F.3d at 250.

Defendants argue that Gilchrist's opinion is unreliable because it does not take into account evidence of subsequent improvement of certain of defendants' patients. However, evidence regarding subsequent improvement of the patients is not determinative of the question of medical necessity at the time of service. See United States ex rel. Schutte v. SuperValu Inc., 598 U.S. 739, 752 (2023) ("[T]he focus is not . . . on post hoc interpretations that might have rendered their claims accurate. It is instead on what the defendant knew when presenting the claim."). Therefore, Gilchrist's failure to review records subsequent to the procedures at issue is immaterial.

[14] Instantaneous flow reserve ("iFR") and fractional flow reserve ("FFR") "are the two primary techniques that can distinguish abnormal or reduced flow down the coronary artery versus normal or non-ischemic blood flow." (Gilchrist Rep. (DE 122-1) at 4-5).

Finally, defendants argue Gilchrist's opinion that the error rate in the CAD sample and PAD sample "appears far more than what would be expected in a random retrospective chart review," (Gilchrist Rep. (DE 122-1) at 3), should be excluded because it relies on incorrect or unavailable data. Defendants point to Tyger Construction for the proposition that "[a]n expert's opinion should be excluded when it is based on assumptions which are speculative and are not supported by the record." 29 F.3d at 142. In that case, an expert opined on the amount of damages suffered by a construction company, including "increased costs caused by time delays associated with a lack of sand." Id. However, there was uncontradicted evidence that a sand stockpile existed at the time in question. Id. at 143. The court held it was an abuse of discretion to admit the expert's testimony that was based on assumption of a fact directly contradicted by the record. Id.

Here, Gilchrist does not make assumptions of fact directly contradicted by the evidence. Instead, he opines on the expected number of unnecessary or unreasonable procedures based on his specialized knowledge and experience as a cardiologist who regularly reviews patient records. (See Gilchrist Dep. (DE 121-3) at 16). Questions about the factual basis of this opinion go to weight and credibility, not admissibility. See Bresler, 855 F.3d at 195.

Plaintiffs have shown by a preponderance of the evidence that Gilchrist is a qualified expert whose testimony is relevant and whose methodology is reliable. See Cooper, 259 F.3d at 199. Pursuant to Rule 702 and Daubert, Gilchrist's testimony is admissible. Accordingly, that portion of defendants' motion which seeks to exclude Gilchrist's testimony is denied.

b. Petron

Petron is qualified as an expert regarding statistical sampling, and defendants do not challenge his expertise or the relevance of his opinions. He was retained by plaintiffs to validate the CAD and PAD samples and to estimate the amount of overpayment derived from those

samples. (Petron Rep. (DE 122-2) ¶ 5). The court finds Petron has sufficient specialized knowledge to qualify as an expert, and his opinions are relevant to the factual question of damages. Therefore, Petron's testimony is admissible if the principles and methodologies he employed are reliable. See Westberry, 178 F.3d at 261. The court concludes that they are.

Petron validated the CAD and PAD samples by examining data files to validate the population of claim lines, the sample frames, and the samples identified by Safeguard. (Id. ¶¶ 14-15). Petron observed that Safeguard "intended to utilize a 90 percent confidence level to select the sample sizes; however, the methodology provided shows [Safeguard] selected the sample sizes based off the 80 percent confidence level." (Id. ¶ 17).[15] During deposition, Petron clarified that Safeguard's "80 percent is equivalent to 90 percent one-sided." (Petron Dep. (DE 121-2) at 68). This is because "[s]tatisticians may use the lower-tail of a two-sided confidence level when the desired outcome is to estimate the lower-limit of a confidence interval." (Petron Aff. (DE 140-9) ¶ 9).[16] Petron concluded that "[t]he procedures employed by [Safeguard] are consistent with those [he] employ[s] when selecting samples," and opined that Safeguard "created valid statistical samples that follow generally accepted statistical guidelines." (Id. ¶ 21).

Defendants challenge the reliability of Petron's opinion on the basis that "the samples drawn by [Safeguard] were drawn using a 'confidence level' that is lower than the confidence level generally accepted in the field." (See Defs.' Mem. Supp. Mot. Exclude Evid. (DE 132) at 24). However, where Petron explained how he determined that "the sample size is the same whether

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15 " 'Confidence' is a term of art. The confidence level indicates the percentage of the time that intervals from repeated samples would cover the true value." David H. Kaye & David A. Freedman, Reference Guide on Statistics, in Reference Manual on Scientific Evidence 211, 247 (Fed. Jud. Ctr. 3d Ed. 2011).

16 By contrast, defendants' expert, Callahan, opined that "[i]t is not mathematically sound or accurate to say that the output for a two-sided 80% confidence level is equal to or the same as a one-sided 90% confidence level." (Callahan Aff. (DE 140-9) ¶ 13). Such competing view espoused by defendants' expert properly goes to the weight of the evidence rather than its reliability, under the circumstances of this case.

you use . . . a two-sided 80% confidence level or . . . a one-sided 90% confidence level," the court finds Petron used reliable statistical methodology. (See Petron Aff. (DE 140-9) ¶ 7). Further, "[g]eneral acceptance is not a necessary precondition to the admissibility of scientific evidence." Daubert, 509 U.S. at 597. Rather, defendants' contention regarding the confidence level used by Petron is an issue that can be raised in cross examination in addressing the relative strength of the opinion of Petron. See Bresler, 855 F.3d at 196. Accordingly, Petron's testimony regarding the validity of the CAD and PAD samples will not be excluded for lack of reliability.

Petron also calculated statistical extrapolations based on the results of Gilchrist's review of the samples. (Petron Rep. (DE 122-2) ¶ 22). To the extent defendants seek to exclude Petron's testimony based on his reliance on Gilchrist's opinion, such argument fails where the court finds Gilchrist's testimony reliable.

According to the United States Centers for Medicare and Medicaid Services ("CMS"), "[i]n most situations, the lower limit of a one-sided 90 percent confidence interval should be used as the amount of overpayment." CMS Medicare Program Integrity Manual (CMS Pub. 100-08), § 8.4.5 (2024). "This conservative procedure incorporates the uncertainty inherent in the sampling design and works to the financial advantage of the provider." Id. Further, "[s]tandard methods for calculating a one-sided 90 percent confidence interval, such as those based on the central limit theorem . . . are generally acceptable." Id.

Here, Petron used Rat-Stats, "a widely accepted free software program developed by the Department of Health and Human Services' Office of the Inspector General," to perform the extrapolations. (Petron Rep. (DE 122-2) ¶ 24). Based on those Rat-Stats extrapolations, Petron estimated overpayments of $313,512 for CAD procedures and $28,215 for PAD procedures, using

the lower limits of the respective 90% confidence intervals. (Id. ¶ 26). These estimates account for respective margins of error of 35.15% and 61.52%.[17] (Id. ¶ 25).

Defendants contend estimates with such a large margin of error are incapable of meeting a preponderance of the evidence standard. There is no indication, however, that the Rat-Stats methods used by Petron are unreliable or that Petron did not appropriately apply those methods to the facts of the case. Defendants' argument about the size of the margin of error goes to the weight of Petron's testimony and is therefore not appropriate at this juncture. See Bresler, 855 F.3d 195. Defendants cite no authority for their assertion that an estimate, derived via valid statistical methods, as here, albeit with a large margin of error, is incapable of meeting a preponderance of the evidence standard.[18] The court declines to so hold.

Plaintiffs have shown by a preponderance of the evidence that Petron is a qualified expert whose testimony is relevant and whose methodology is reliable. See Cooper, 259 F.3d at 199. Pursuant to Rule 702 and Daubert, Petron's testimony is admissible. That portion of defendants' motion which seeks to exclude Petron's testimony is denied.

c. Patterson

Plaintiffs argue that the report by Patterson does not comply with the procedural requirements of Rule 26(a)(2)(B). However, plaintiffs do not point to any testimony from

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[17] A margin of error is one method of measuring the precision of a sample. Statistical Sampling: A Toolkit for MFCUs, U.S. Department of Health and Human Services Office of Inspector General at 12 (September 2018), https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/files/mfcu%20sampling%20guidance%20final.pdf [https://perma.cc/BD7E-JASJ]. The margin of error is often expressed as the distance between the upper or lower limit of the confidence interval and the point estimate. Id. at 18.

[18] Indeed, the preponderance of the evidence standard only requires a showing of a fact "more likely than not" or, in other words, greater than 50%. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 329 (2007). The margin of error is a measure of precision, not accuracy. Statistical Sampling, supra note 17, at 12. "There is no bright-line statistical rule for how precise a sample needs to be to reasonably rely on the point estimate." Id. Additionally, where, as here, the estimate refers to the lower bound of the confidence interval, a higher margin of error results in a smaller estimated value than would be produced with a smaller margin of error. (See Petron Rep. (DE 122-2) ¶ 25 n.22).

Patterson that was not included in report provided by defendants or that came as an "unfair surprise." Bresler, 855 F.3d at 190. Therefore, the report complies with the procedural requirements of the Rule, and Patterson's testimony will not be excluded on that basis.

Plaintiffs also argue Patterson is unqualified to testify about billing requirements. Patterson's opinion, however, concerns the procedures at issue in this matter, more broadly, and not just billing requirements. (See Patterson Rep. (DE 124-4) ¶ 1). For the opinion he gives, Patterson is qualified to testify. He is board-certified in cardiovascular medicine and is a professor of cardiovascular medicine. (Id. ¶ 2). He has published peer-reviewed articles and lectured on interventional cardiology, cardiac angiography intervention, and cardiac catheterization. (Id.). His "specialized knowledge" of cardiology will help the trier of fact understand the cardiovascular diseases relevant to this matter and determine whether the procedures at issue were reasonable and necessary. Fed. R. Evid. 702. Therefore, the court finds Patterson qualified to testify about the procedures at issue in this matter.

Patterson's opinion that the 30 procedures at issue met the applicable standard of care is relevant to the question of whether those procedures were reasonable and necessary. According to CMS, a medical service is reasonable and necessary if it is, among other things, "furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition." CMS Medicare Program Integrity Manual (CMS Pub. 100-08), § 13.5.4 (2019). Therefore, Patterson's testimony is "sufficiently tied to the facts of the case" and will not be excluded for relevance. Daubert, 509 U.S. at 591.

Patterson applied his medical expertise to the facts of the case by reviewing medical records and imaging as well as Gilchrist's report and testimony and the deposition testimony of

the individual defendants. (Patterson Rep. (DE 124-4) Ex. 2). The court finds this methodology reliable.

Defendants thus have established by a preponderance of the evidence that Patterson is a qualified expert whose testimony is relevant and whose methodology is reliable. See Cooper, 295 F.3d at 199. Pursuant to Rule 702 and Daubert, Patterson's testimony is admissible, and that portion of plaintiffs' motion which seeks to exclude Patterson's testimony is denied.

d. Holland

Defendants provided a report by Holland as required by Rule 26(a)(2)(B). Plaintiffs argue that Holland improperly expanded his opinions during deposition to include "medical necessity opinions that had not been adequately addressed in his report." (DE 113 at 22). However, where Holland's report included his opinion that "the decisions made by the physicians of Ferncreek Cardiology were appropriate," (DE 124-3 at 5), plaintiffs have not demonstrated an "unfair surprise" by his subsequential medical necessity testimony, Bresler 855 F.3d at 190. Therefore, the report complies with the Rule, and Holland's testimony will not be excluded on that basis.

Plaintiffs argue Holland is unqualified to testify about billing requirements. As with Patterson, Holland's opinion concerns the procedures at issue in this matter, more broadly, and not just billing requirements. (See Holland Rep. (DE 124-3) at 3-6). For the opinion he gives, Holland is qualified to testify. He is board-certified in internal medicine, cardiovascular diseases, and interventional cardiology. (Id. at 2). His "specialized knowledge" in these areas will help the trier of fact understand the cardiovascular diseases relevant to this matter and determine whether the procedures at issue were reasonable and necessary. Fed. R. Evid. 702. Therefore, the court finds Holland qualified to testify about the procedures at issue in this matter.

Holland's report need not classify every procedure as "reasonable and necessary" to be relevant. Ultimately, the question of whether the procedures were reasonable and necessary is one for the jury, and Holland's opinion that they were appropriate is "sufficiently tied to the facts of the case" to assist the jury in that determination. Daubert, 509 U.S. at 591. Therefore, Holland's testimony will not be excluded for relevance.

Holland applied his specialize knowledge in cardiology to the facts of the case by reviewing patient records, Gilchrist's report, and deposition testimony of Gilchrist and the individual defendants. (Holland Rep. (DE 124-3) Ex. 2). The court finds this methodology reliable.

Defendants have established by a preponderance of the evidence that Holland is a qualified expert whose testimony is relevant and whose methodology is reliable. See Cooper, 295 F.3d at 199. Pursuant to Rule 702 and Daubert, Holland's testimony is admissible, and that portion of plaintiffs' motion which seeks to exclude Holland's testimony is denied.

e. Callahan

Defendants provided a report by Callahan as required by Rule 26(a)(2)(B). Plaintiffs do not point to any testimony from Callahan that was not included in this report. Therefore, the report complies with the Rule, and Callahan's testimony will not be excluded on that basis.

Callahan is a certified public accountant (CPA) and certified forensic examiner and has been recognized as an expert in forensic accounting and damages. (Callahan Rep. (DE 113-6) ¶¶ 14, 16). Callahan testified that he "uses sampling methodologies and practices for purposes of determining damages." (Callahan Dep. (DE 133-1) at 185). His specialized knowledge in this area will help the trier of fact understand the question of damages. Thus, Callahan is qualified as an expert in using sampling to determine damages.

Plaintiffs do not challenge the relevance of Callahan's testimony. However, to the extent his testimony addresses extrapolation of damages for the individual defendants or to times after 2017, such testimony is irrelevant where plaintiffs no longer seek such damages.

Callahan was engaged by defendants to analyze documents, conduct independent research and analysis, and provide his opinion regarding Petron's report. (Callahan Rep. (DE 113-6) ¶ 2). Callahan relied upon the amended complaint in intervention, deposition testimony of relator and the individual defendants, and the expert reports and exhibits of Gilchrist and Petron. (Callahan Rep. (DE 113-6) Attach. II). Callahan did not perform any statistical calculations or tests. Instead, he scrutinized Petron's report, and provided his opinion that Petron's analysis relied on flawed assumptions. (Id. ¶ 33). Callahan also relied on his own experience to opine that the margins of error in Petron's extrapolations are high. (Id. ¶ 43). There is not an "analytical gap" requiring the court to exclude Callahan's opinions as ipse dixit. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997).

Defendants have established by a preponderance of the evidence that Callahan is a qualified expert whose testimony is relevant and whose methodology is reliable. Pursuant to Rule 702 and Daubert, Callahan's testimony is admissible, and that portion of plaintiffs' motion which seeks to exclude Callahan's testimony is denied.

B. Motions for Summary Judgment

1. Standard of Review

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The party seeking summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it

believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

Once the moving party has met its burden, the non-moving party must then "come forward with specific facts showing that there is a genuine issue for trial." Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986). Only disputes between the parties over facts that might affect the outcome of the case properly preclude the entry of summary judgment. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247–48 (1986) (holding that a factual dispute is "material" only if it might affect the outcome of the suit and "genuine" only if there is sufficient evidence for a reasonable jury to return a verdict for the non-moving party).

"[A]t the summary judgment stage the [court's] function is not [itself] to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Id. at 249. In determining whether there is a genuine issue for trial, "evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in [non-movant's] favor." Id. at 255; see United States v. Diebold, Inc., 369 U.S. 654, 655 (1962) ("On summary judgment the inferences to be drawn from the underlying facts contained in [affidavits, attached exhibits, and depositions] must be viewed in the light most favorable to the party opposing the motion.").

Nevertheless, "permissible inferences must still be within the range of reasonable probability, ... and it is the duty of the court to withdraw the case from the [factfinder] when the necessary inference is so tenuous that it rests merely upon speculation and conjecture." Lovelace v. Sherwin-Williams Co., 681 F.2d 230, 241 (4th Cir. 1982). Thus, judgment as a matter of law is warranted where "the verdict in favor of the non-moving party would necessarily be based upon speculation and conjecture." Myrick v. Prime Ins. Syndicate, Inc., 395 F.3d 485, 489 (4th Cir. 2005). By contrast, when "the evidence as a whole is susceptible of more than one reasonable

inference, a [triable] issue is created," and judgment as a matter of law should be denied. Id. at 489–90.

B. Analysis

In opposition to the instant motions for summary judgment, plaintiffs state they withdraw their state law claims for common law fraud, unjust enrichment, and payment by mistake, as well as certain portions of the remaining claims.[19] This leaves the following claims for consideration: violation of the False Claims Act and NCFCA by 1) submission of false Medicare and Medicaid claims in the years 2014 to 2017, 2) false statements material to a false claim in the same time period, and 3) conspiracy.

The False Claims Act "imposes liability on anyone who 'knowingly' submits a 'false' claim to the [g]overnment." Schutte, 598 U.S. at 742 (citing 31 U.S.C. § 3729(a)(1)(A)). It likewise imposes liability on anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).[20] Establishing liability for either type of "claim under the False Claims Act require[s] four elements: 1) a false statement or fraudulent course of conduct; 2) made or carried out with the requisite scienter; 3) that was material; and 4) that caused the government to pay out money or to forfeit moneys due." United States ex rel. Nicholson v. MedCom Carolinas, Inc., 42 F.4th 185, 193 (4th Cir. 2022). Where defendants do not challenge materiality, the court addresses the falsity, scienter, and damages elements in turn.

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[19] Plaintiffs withdraw claims under the False Claims Act and NCFCA for payments made by TRICARE as well as payments made during the years 2018 and 2019. (Gov. Opp. Def. Ferncreek's Mot. Summ. J. (DE 135) at 2). The court addresses the remaining portions of the False Claims Act and NCFCA claims in the analysis herein.

[20] The False Claims Act also imposes liability on anyone who conspires to submit false claims or false records. 31 U.S.C. § 3729(a)(1)(C). Defendants assert liability for conspiracy under this subparagraph is dependent on proof of violation of either of the prior subparagraphs. Because the court determines defendants are not entitled to summary judgment on the false claims and false records counts, it does not address this argument regarding conspiracy.

1. Falsity

"The phrase 'false or fraudulent claim' in the False Claims Act should be construed broadly." Harrison v. Westinghouse Savannah River Co. (Harrison I), 176 F.3d 776, 788 (4th Cir. 1999). Here, plaintiffs do not allege that defendants presented claims for services which were factually false, i.e. not actually performed. Rather, plaintiffs allege defendants performed and submitted claims for services which were not medically necessary and certified that such procedures were medically necessary. (See Mem. U.S. & N.C Opp. Ferncreek's Mot. Summ. J. ("Pls' Opp. Br.") (DE 135) at 3). This theory of liability is known as "implied false certification." Universal Health Servs., Inc. v. U.S. ex rel Escobar, 579 U.S. 176, 180 (2016). Under this theory, "liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." Id. at 181. "A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the [g]overnment's payment decision in order to be actionable under the False Claims Act." Id.

Medicare and Medicaid will compensate providers only for services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 440.230(d) (2011). The United States Centers for Medicare and Medicaid Services ("CMS") has determined that services that are 1) safe and effective, 2) not experimental, 3) performed within "accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member", should be considered "reasonable and necessary." CMS Medicare Program Integrity Manual (CMS Pub. 100-08), § 13.5.4 (2019).

Here, plaintiffs have provided evidence that defendants submitted claims for procedures that were not medically necessary. For example, Gilchrist opines "23 [CAD] procedures appeared to be not reasonable or necessary," and "Seven (7) of the [PAD] procedures appeared not reasonable." (Gilchrist Rep. (DE 140-2) at 2). Likewise, Marwali asserts "Ferncreek performed medically unnecessary cardiac catheterization procedures during the time [he] worked for Ferncreek," and he "believe[s] the practice was performing unnecessary CAD catheterizations and PAD catheterizations [sic] procedures." (Marwali Aff. (DE 139-14) ¶¶ 4, 6). Relator asserts "patients were subjected to cardiac catheterization despite normal stress tests." (Devarapally Dep. (DE 139-13) at 25). This is evidence of "implied false certification." Escobar, 579 U.S. at 180. Thus, there is a genuine dispute of material fact as to the falsity of defendants' claims.

2. Scienter

"The [False Claims] Act's scienter requirement defines 'knowing' and 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.' " Escobar, 579 U.S. at 182 (quoting 31 U.S.C. § 3729(b)(1)). The NCFCA similarly defines "knowing" and "knowingly" as "Whenever a person, with respect to information, does any of the following: a) Has actual knowledge of the information, b) Acts in deliberate ignorance of the truth or falsity of the information, [or] c) Acts in reckless disregard of the truth or falsity of the information." N.C. Gen. Stat. § 1-606(4). "[N]o proof of specific intent to defraud" is required. 31 U.S.C. § 3729(b)(1)(B); see also N.C. Gen. Stat. § 1-606(4) ("Proof of specific intent to defraud is not required."). "In short, either actual knowledge, deliberate ignorance, or recklessness will suffice." Schutte, 598 U.S. at 750.

"[T]he term 'actual knowledge' refers to whether a person is 'aware of' information." Id. at 751. "[T]he term 'deliberate ignorance' encompasses defendants who are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statement's truth or falsity." Id. Finally, "the term 'reckless disregard' similarly captures defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway." Id.

Here, relator testified about a meeting with defendants Sinna, Daka, and Jayawardena during which defendant Sinna mentioned "falsifying the patient's symptoms in order to get the carotid imaging and also the lower extremity or the leg imaging, which generates more revenue." (Devarapally Dep. (DE 139-13) at 8-9). Relator also testified that defendants "made a rule that every single patient needs to undergo [an] angiogram" when they present with positive troponin. (Id. at 11). Relator "emailed them back saying that's not what would be the right thing to do." (Id.). Relator specifically told defendants that doing catheterizations based solely on positive troponins "would be medically unnecessary." (Id. at 17). Marwali also testified that he "discussed [his] concerns regarding whether the disproportionate number of catheterization procedures were medically necessary with Ferncreek owners Dr. Jayawardena, Dr. Daka, Dr. Sinna, and Dr. Thomas." (Marwali Aff. (DE 139-14) ¶ 7). This testimony tends to show that defendants were "aware of a substantial risk" that at least some of the procedures they were performing were not medically necessary. Schutte, 598 U.S. at 751.

Defendants' reliance on Schutte is unavailing. In that case, the Court held that if plaintiffs establish subjective scienter, including deliberate ignorance or reckless disregard, "then it does not matter whether some other, objectively reasonable interpretation" of the regulatory language would point to a lack of the requisite knowledge. Schutte, 598 U.S. at 757. Accordingly, plaintiffs

here must put forth evidence of defendants' "actual knowledge, deliberate ignorance, or recklessness" regarding the medical necessity of the procedures at issue. Id. at 750. Plaintiffs have done so in the testimony of relator and Marwali.

Plaintiffs have provided evidence that defendants acted with reckless disregard to the truth or falsity of claims they submitted, and defendants dispute this evidence. Therefore, genuine disputes of material fact exist, and summary judgment is not warranted on the question of scienter.

Defendant Thomas relies upon comparison to United States v. Prabhu, 442 F. Supp. 2d 1008 (D. Nev. 2006), and United States ex rel. Becker v. Westinghouse Savannah River Co., 305 F.3d 284 (4th Cir. 2002), in arguing that the government's prior knowledge of his allegedly false claims negates the scienter requirement. In Becker, however, it was not the government's knowledge of the allegedly false claims that negated scienter, but the fact that the defendant changed its reporting codes at the explicit direction of the United States Department of Energy. Id. at 287. Similarly in Prabhu, the defendant complied with the government's instructions to bill for a specific test. 442 F. Supp 2d at 1030. Here, although KEPRO informed defendant Thomas that his "obligations to KEPRO and the Centers for Medicare & Medicaid Services in this matter are fulfilled," (DE 121-23 at 2), there is no indication that KEPRO, CMS, or any other government agency directed defendant Thomas to submit particular claims for payment. Therefore, a genuine issue of material fact remains as to defendant Thomas's scienter.

3. Damages

Plaintiffs must "prove all essential elements of the cause of action, including damages, by a preponderance of the evidence." 31 U.S.C. § 3731(d); N.C. Gen. Stat. § 1-615(c). Plaintiffs seek damages against the individual defendants only for the allegedly false claims within the CAD and PAD samples, not damages extrapolated to the universe of claims. (DE 136 at 18, 21, 23-24,

29). Defendants have not provided evidence to dispute the amounts directly attributable to the procedures within the CAD and PAD samples.

Plaintiffs seek damages against defendant Ferncreek based on Petron's testimony and extrapolation calculations. (Pls' Opp. Br. (DE 135) at 7). Defendants argue that plaintiffs cannot meet the preponderance of evidence standard because the margins of error in Petron's calculations are too high. (Def. Ferncreek Mem. Supp. Mot. Summ. J. (DE 115) at 24). This argument misses the mark because "at the summary judgment stage the judge's function is not [her]self to weigh the evidence." Anderson, 477 U.S. at 249. It is sufficient that plaintiffs have "come forward with specific facts showing that there is a genuine issue for trial." Matsushita, 475 U.S. at 587.

In sum, there are genuine issues of material fact regarding falsity, scienter, and damages as to each defendant. Summary judgment is therefore inappropriate, and defendants' motions for summary judgment are denied.

CONCLUSION

Based on the foregoing, the parties' motions to strike expert opinions (DE 112, 131) and defendants' motions for summary judgment (DE 114, 117, 125, 127, 129) are DENIED. Where claims remain for trial, in accordance with case management order entered April 25, 2023, as amended August 19, 2024, this case is now ripe for entry of an order governing deadlines and procedures for final pretrial conference and trial. The parties are DIRECTED to confer and file within **21 days** from the date of this order a joint status report informing of 1) estimated trial length; 2) particular pretrial issues which may require court intervention in advance of trial, if any; and 3) at least three suggested alternative trial dates. The parties shall specify if they wish to schedule a

court-hosted settlement conference or additional alternative dispute resolution procedures in advance of trial, and if so the date for completion of such.

SO ORDERED, this the 20th day of March, 2025.

LOUISE W. FLANAGAN
United States District Judge